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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,880	12/21/2001	Beate Hoffmann	CHEP:003US	4492

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,880	HOFFMANN ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-51* is/are pending in the application.

4a) Of the above claim(s) *44-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-43,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group I invention, drawn to a nucleic acid, a recombinant vector, a recombinant host cell, a recombinant or transgenic plant or seed in the reply filed on May 24, 2004 is acknowledged.

Claims 1-25 were cancelled in the preliminary amendment filed December 21, 2001.

Claims 27-51 were newly added in the preliminary amendment filed December 21, 2001.

Claims 26-51 are pending.

Claims 44-49 are withdrawn from consideration.

Claims 26-43 and 50-51 are examined.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed May 6, 2002, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-28, 30-38, 40-43 and 50-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated or purified nucleic acid comprising a plant promoter comprising a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof including a nucleic acid comprising a different sequence from that entered under the reference No. AC 007 289 in the EMBL database, a nucleic acid comprising all or part of a polynucleotide hybridizing under hybridization conditions of high stringency with the nucleotide sequence SEQ ID No. 1 or the complement thereof. The claims are also drawn to an isolated nucleic acid comprising 200 to 2000 consecutive nucleotides of a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof, which nucleic acid is further defined as a promoter, a vector comprising a polynucleotide sequence possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof including a vector substantially identical to a vector contained in an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218, a recombinant host cell comprising said vector, a recombinant or transgenic plant comprising a polynucleotide sequence possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof.

The specification describes SEQ ID NO:1 as a 2149 bp polynucleotide identified by promoter trapping and obtained from Arabidopsis thaliana and functioning to drive root-specific

expression of an operably linked GUS reporter gene in transgenic Arabidopsis plants (sequence listing; pages 25-30 Examples 1-4). The specification also describes SEQ ID NO:1 as having the following sequence motifs: two TGACG motifs corresponding to the binding site of the root-specific factor Asfl in the 355 promoter of the CaMV (position 1000-1004 and 1866-1870), two motifs close, to within one nucleotide, to enhancer sequences of the same 355 promoter (position 28-35: CTGAAAG instead of GTGAAAG and 25 position 882-889: GTGCTTTG instead of GTGGTTTG) and 3G-box ACGT (positions 285-288, 604-607, 1107-11 10), 21 TATA motifs and 9 CAAT motifs (page 13; Figure 1; sequence listing). The specification describes SEQ ID NO:3 as a 4413 bp genomic DNA fragment comprising SEQ ID NO:1 that was obtained from an Arabidopsis thaliana genomic DNA library using SEQ ID NO:1 as probe (sequence listing; pages 26-28 Example 2). The specification also describes SEQ ID NO:3 as being very rich in bases A and T (68% of A and T) and containing 67 ATG motifs, 20 CAAT motifs, 38 TATA motifs, 9 TATAAT motifs and 2 Cr boxes (sequence listing; page 28).

The specification does not describe other isolated promoter polynucleotides possessing at least 80% nucleotide identity with a fragment of at least 200 unspecified consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof. The specification does not describe isolated promoter polynucleotides as comprising a different sequence from that entered under the reference No. AC 007 289 in the EMBL database. The specification does not describe recombinant host cells, plants or transgenic plants. The specification does not describe other isolated promoter polynucleotides comprising all or part of a polynucleotide hybridizing under hybridization conditions of high stringency with the nucleotide sequence SEQ ID No. 1 or the complement thereof. The specification does not describe other isolated promoter polynucleotides

comprising 200 to 2000 unspecified consecutive nucleotides of a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 unspecified consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof. The specification does not describe a vector substantially identical to a vector contained in an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218, or what aspects of the deposited vector would be characteristic of other vectors "substantially identical" thereto. The specification does not describe recombinant host cells, plants or transgenic plants comprising said promoter polynucleotides or vectors.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The requirements for describing a genus of promoter polynucleotides are analogous to those for describing cDNA polynucleotides. In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses promoter polynucleotides obtained from any source that have at least 80% identity with fragments of at least 200 unspecified consecutive nucleotides of SEQ ID NO:1 or its complement, and promoter polynucleotides obtained from any source that comprise 200 to 2000 unspecified consecutive nucleotides of a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 unspecified consecutive nucleotides of a nucleotide

sequence SEQ ID No. 1 or its complement, nor the structural features unique to the genus, as Applicant has described but a single polynucleotide that has promoter function, a polynucleotide of SEQ ID NO:1.

Claims 35 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 35 is drawn to the vector of claim 34, further defined as being substantially identical to a vector contained in an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218. Claim 39 is drawn to the cell of claim 36, further defined as a cell of an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218.

It is apparent that a cell of an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218, and the vector contained therein, are required to practice the claimed invention. As such they must be obtainable by a repeatable method set forth in the specification, or otherwise be readily available to the public. If the vector and cell are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof.

The specification does not disclose a repeatable process to obtain the exact same vector and cell in each occurrence, and it is not apparent if the vector and cell are readily available to the public. It is noted that applicants have deposited the vector and cell with the NCCM under the access No. 1-2218, but there is no indication in the specification as to public availability. If the deposit of the vector and cell was made under the terms of the Budapest Treaty, then an

affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the vector and cell will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see 37 CFR § 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

Claims 26-34, 36-38, 40-43 and 50-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated or purified nucleic acid comprising a plant promoter comprising the nucleotide sequence SEQ ID No. 1, does not reasonably provide enablement for other promoter nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated or purified nucleic acid comprising a plant promoter comprising a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof including a nucleic acid comprising a different sequence from that entered under the reference No. AC 007 289 in the EMBL database, a nucleic acid comprising all or part of a polynucleotide hybridizing under hybridization conditions of high stringency with the nucleotide sequence SEQ ID No. 1 or the complement thereof, a nucleic acid comprising the polynucleotide extending from the nucleotide at position 1 to the nucleotide at position 2400 of the sequence SEQ ID No. 3; the polynucleotide extending from the nucleotide at position 493 to the nucleotide at position 2400 of the sequence SEQ ID No. 3; the polynucleotide extending from the nucleotide at position 1076 to the nucleotide at position 2400 of the sequence SEQ ID No. 3; the polynucleotide extending from the nucleotide at position 1976 to the nucleotide at position 2400

of the sequence SEQ ID No. 3; and the polynucleotide extending from the nucleotide at position 2040 to the nucleotide at position 2400 of the sequence SEQ ID No. 3. The claims are also drawn to an isolated nucleic acid comprising 200 to 2000 consecutive nucleotides of a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof, which nucleic acid is further defined as a promoter, a vector comprising a polynucleotide sequence possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof including a vector substantially identical to a vector contained in an E. coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218, a recombinant host cell comprising said vector, a recombinant or transgenic plant comprising a polynucleotide sequence possessing at least 80% nucleotide identity with a fragment of at least 200 consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof.

The specification discloses the identification by promoter trapping of a 2149 bp polynucleotide of SEQ ID NO:1 in *Arabidopsis thaliana*, and the use of SEQ ID NO:1 to drive root-specific expression of an operably linked GUS reporter gene in transgenic *Arabidopsis* plants (Figures 3, 4 and 6; pages 25-30 Examples 1-4; page 34 Table 1). The specification discloses the isolation of a 4413 bp genomic DNA fragment of SEQ ID NO:3 that comprises SEQ ID NO:1 by screening an *Arabidopsis thaliana* genomic DNA library with SEQ ID NO:1 (pages 26-28 Example 2). The specification also discloses how to make expression constructs comprising the following fragments of SEQ ID No. 3: the fragment extending from the nucleotide at position 1 to the nucleotide at position 2400 of the sequence SEQ ID No. 3, the

fragment extending from the nucleotide at position 493 to the nucleotide at position 2400 of the sequence SEQ ID No. 3, the fragment extending from the nucleotide at position 1076 to the nucleotide at position 2400 of the sequence SEQ ID No. 3, the fragment extending from the nucleotide at position 1976 to the nucleotide at position 2400 of the sequence SEQ ID No. 3, and the fragment extending from the nucleotide at position 2040 to the nucleotide at position 2400 of the sequence SEQ ID No. 3, but the specification does not disclose which of these fragments, if any, has promoter activity, or the quality of the promoter function they exhibit (pages 30-33 Example 5).

The specification also does not disclose other isolated promoter polynucleotides that possess at least 80% nucleotide identity with a fragment of at least 200 unspecified consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof, or how to make or use such polynucleotides. The specification does not disclose isolated promoter polynucleotides that comprise a different sequence from that entered under the reference No. AC 007 289 in the EMBL database, or how to make or use such polynucleotides. The specification does not disclose other isolated promoter polynucleotides comprising all or part of a polynucleotide hybridizing under hybridization conditions of high stringency with the nucleotide sequence SEQ ID No. 1 or the complement thereof, or how to make or use such polynucleotides. The specification does not disclose other isolated promoter polynucleotides comprising 200 to 2000 unspecified consecutive nucleotides of a polynucleotide possessing at least 80% nucleotide identity with a fragment of at least 200 unspecified consecutive nucleotides of a nucleotide sequence SEQ ID No. 1 or the complement thereof or how to make or use such polynucleotides. The specification does not disclose a vector substantially identical to a vector contained in an E.

coli strain deposited with the NCCM on 25 May 1999 under the access No. 1-2218, or how to make or use such a vector.

The full scope of the claimed invention is not enabled because it is unpredictable whether a particular polynucleotide would function as promoter, or as a root-specific promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the polynucleotide, which nucleotides and motifs may not be present in subfragments of SEQ ID NOS:1 or 3, or in polynucleotides having only 80% identity to SEQ ID NO:1 or its subfragments.

Subfragments of SEQ ID NOS:1 or 3 and polynucleotides having only 80% identity to SEQ ID NO:1 or its subfragments may lack key nucleotides required for basal promoter function. See, for example, Kim et al. (Plant Molecular Biology, 1994, Vol. 24, pages 105-117), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

Subfragments of SEQ ID NOS:1 or 3 and polynucleotides having only 80% identity to SEQ ID NO:1 or its subfragments may also lack key nucleotide motifs required for tissue-specific promoter function. See, for example, Verdaguer et al. (Plant Molecular Biology, 1998,

Vol. 37, pages 1055-1067), who teach that different regions of the Cassava vein mosaic virus (CsVMV) are required to confer different types of tissue specificities on the isolated CsVMV promoter. Verdaguer et al. teach that a region encompassing nucleotides -222 to -173 of the CsVMV promoter contains cis elements that control promoter expression in roots (page 1057 Figure 1, page 1065 Figure 6 and column 2 first full paragraph).

In the instant case Applicant has not provided guidance with respect whether subfragments of SEQ ID NOS:1 or 3 retain the key nucleotides and regulatory regions required for the basal or tissue-specific promoter function of SEQ ID NO:1. Applicant also has not provided guidance with respect to how to obtain polynucleotides having only 80% identity to SEQ ID NO:1 or its subfragments that retain the functionality of SEQ ID NO:1, i.e. , that retain the key nucleotides and regulatory regions of SEQ ID NO:1 required for basal or tissue-specific promoter function. Absent such guidance it would require undue experimentation for one skilled in the art to use subfragments of SEQ ID NOS:1 or 3, as one skilled in the art would have to determine whether and what kind of promoter function subfragments of SEQ ID NOS:1 or 3 exhibit, and/or how to modify subfragments of SEQ ID NOS:1 or 3 to achieve the type of promoter function desired. Absent such guidance it would also require undue experimentation for one skilled in the art to make and use polynucleotides having only 80% identity to SEQ ID NO:1 or its subfragments, as one skilled in the art would have to isolate from undisclosed sources and/or construct polynucleotides having at least 80% identity to SEQ ID NO:1 or its subfragments, and test each sequence for promoter function in plant cells, and for its pattern of expression in plant tissues, in order to discriminate between those polynucleotides that have the desired functional properties and those that do not.

Remarks

No claim is allowed.

Claims 26-43 and 50-51 are deemed free of the prior art, due to the failure of the prior art to teach or suggest an isolated nucleic acid of SEQ ID NO:1 or SEQ ID NO:3, the recited subfragments of SEQ ID NO:3, or an isolated nucleic acid comprising a plant promoter comprising a polynucleotide possessing at least 80% nucleotide sequence identity with a fragment of at least 200 consecutive nucleotides of SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  8/7/04